National Reforms to Clinical Trials

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Message from Emeritus Professor Ian Chubb AC FAA FTSE
Chair, Inter-Governmental Policy Reform Group (IGPRG)

Dear colleagues,

I am pleased to share an update on the national initiatives to strengthen, harmonise and streamline health and medical research in Australia. We are making good progress.

Next week I am hosting IGPRG in Canberra. I'm looking forward to discussing implementation of the National Clinical Trials Governance Framework, the third edition of the NSQHS Standards, and progress of the National One Stop Shop.

Regards,

Ian.

One stop for national reform information

Information on national reforms that will improve the health and medical research operating and regulatory environment and lead to a stronger, easier and more consistent approach to health research is now available on the Australian Clinical Trials website. The National reforms section includes information on the:

- National One Stop Shop
- Accreditation for Human Research Ethics Committees
- National Standard Operating Procedures for Clinical Trials in Australia
- National Clinical Trials Governance Framework
- Inter-Governmental Policy Reform Group.

The website is an important channel for providing information and updates on the national reform agenda.

National One Stop Shop progress

Pre-delivery design workshops continue, with representatives from across the sector sharing their experience and providing feedback on the system workflows and prototypes.

There has been significant interest and engagement in the first phase of workshops. We have covered the user experience and data considerations around:

- System personas and user landing pages
- User registration and organisational profiles
- Project and Application Initiation, and
- Feasibility Assessment

Future engagement will cover the end-to-end user journey informing the system design and functionality refinement.

Your questions answered

The following questions have been recently raised through the workshops. You can also find

answers to common questions in earlier newsletters.

What safeguards will ensure data security and privacy?

The system will comply with national cybersecurity standards and privacy legislation, ensuring data is protected and secure. For example, role-based access control (RBAC) and multi-factor authentication to manage user permissions securely.

All user activity will be logged for transparency and auditing. Industry standards such as Advanced Encryption Standard (AES)-256 and Transport Layer Security (TLS) 1.2+ will be used to encrypt data in storage and during transfer. Only authorised users will see their organisation's data and user actions will be logged for auditing and compliance.

How will NOSS support strong cultural governance and Indigenous Data sovereignty?

The design and implementation will be guided by the principles outlined in the Framework for Governance of Indigenous Data.

What is the approach to data migration and legacy system integration?

A data migration strategy will be developed collaboratively with jurisdictions to ensure a smooth transition. Each jurisdiction will have a tailored migration plan based on their existing systems and data structures.

How will the system manage users who are affiliated with multiple organisations?

NOSS will support multiple roles per user and multi-affiliation across organisations and jurisdictions. If someone is linked to more than one organisation, they can switch between organisations as needed.

Each organisation membership is managed independently, meaning the user will have access and permissions based on their assigned roles within each organisation. This allows users to perform tasks and access information relevant to each specific organisation they are associated with.

How will data consistency be supported?

NOSS will enable profiles to be created once and reused across feasibility assessment, all initiated applications, and monitoring stages. This will reduce duplicate entries and improve the efficiency of the application process by auto-filling the application forms.

Where can I find more information?

You can keep up to date with the national reforms to improve the health and medical research regulatory and operating environment by signing up to our newsletter, visiting our website, and participating in further consultations.

Accreditation for Human Research Ethics Committees

Public consultation on the draft quality standards and accreditation scheme ended on 17 April 2025. We appreciate everyone who took the time to review the information and make a submission. The quality standards aim to build on Australia's strong reputation of high ethical integrity, while driving consistency and efficiency of ethics reviews.
Each standard lists:

- the actions against which HRECs will be assessed for accreditation
- suggested strategies to meet the actions
- examples of evidence that show how the HREC is meeting the actions.

We are currently refining the model in consultation with the Ethics Advisory Group and considering the feedback received. A consultation report will be published shortly.

National Clinical Trials Governance Framework

The Governance Framework is a key reform initiative to help drive national consistency in the delivery and governance of clinical trials. Increased consistency helps position Australia as a lead destination for health and medical research.

The ACSQHC recently conducted two webinars on the implementation of the Governance Framework:

- Process of Assessment and Resources
- Exemplar Assessments in Practice.

The Self-assessment tool helps health service organisations implement the Governance Framework.

2025 National Statement

On 1 April 2025, NHMRC released an updated National Statement on Ethical Conduct in Human Research 2025 (National Statement) containing changes to Section 4 Ethical considerations specific to participants in research and minor changes to other sections of the National Statement.

The 2025 National Statement will take effect on 1 October 2025. Researchers, reviewers and other stakeholders should make any necessary adjustments to policy, processes or individualised application or project description templates in place in preparation for the effective date.

Global Action Plan for clinical trial ecosystem strengthening

The World Health Organization's (WHO's) Global Action Plan for clinical trial ecosystem

strengthening, released on 21 April 2025, sets out nine key action areas to improve conduct and management of clinical trials. It supports implementation of WHO's guidance for best practices for clinical trials aiming to build sustainable, efficient, and inclusive clinical trial ecosystems that generate high-quality evidence to inform policy and practice.

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